DETAILED ACTION

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-125 were rejected in the Office Action entered on 20 April 2009.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2009 has been entered.

The 15 October 2009 submission has amended claim 125.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-125 are pending in this application.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-125 are rejected.

Information Disclosure Statement

1. The Information Disclosure Statement submitted on 21 January 2009 was not considered in the previous Office Action for reasons stated therein.

The presently filed RCE has rectified the issues related to the 21 January 2009 IDS. Accordingly, the 21 January 2009 IDS has been considered by the Examiner.

Response to Remarks - 35 USC § 112

2. In response to the amendments to claim 125, the previous rejection of claim 125 under 35 U.S.C. § 112, second paragraph, is withdrawn.

Response to Remarks - 35 USC § 103

3. In response to the previous rejection of claims 1-3, 5-7, 9-10, 14, 15, 16-18, 20-22, 24-25, 29, 30-37, 41, 42, 54, 56, 58-60, 62-63, 67-70, 72, 74-76, 78-79, 83-86, 88-92, 96-98, 112-119, and 124-125 under 35 U.S.C. § 103(a) as being unpatentable of Whitcher in view of St. Ville, Applicants submit several arguments. Among those, Applicants argue that:

> St. Ville discusses a geometry generator, but does not teach or suggest a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system. Nor does Whitcher as discussed above. As such, St. Ville also fails to teach or suggest a mesh generator that receives a geometric model of an anatomical feature of at least one vascular system and a medical device. Whitcher also fails to teach or suggest such a mesh generator.

This argument has been fully considered and has been found persuasive. Accordingly, the previous rejection has been withdrawn. New grounds of rejection are entered below.

Additionally, Applicants argue that Whitcher does teach or suggest a stress/strain/deformation analyzer that receives a finite element model or mesh representing a geometric model of an anatomical feature and a medical device. This argument is persuasive only in part because Whitcher plainly teaches a stress/strain/deformation analyzer that receives a finite element model or mesh representing a geometric model of a medical device [See Whitcher, FIG. 3 "Stent Geometry"]. A finite element model or mesh representing an anatomical feature is taught elsewhere in the prior art (see new grounds of rejection entered below).

Additionally, Applicants argue that, in Whitcher, there is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between an anatomical feature and a medical device over at least one dynamic expansion and contraction cycle. This argument is unpersuasive because Whitcher expressly teaches that [*"In the arteries, the cyclical difference between systolic and diastolic pressures generates the most significant forces on the stent... The lading conditions for this analysis therefore consider only the preload and pulsatile radial forces on the structure."* (Whitcher, page 1009, "5. Boundary and Loading Conditions")]. Where Applicants claim recites "dynamic expansion and contraction cycle," Whitcher teaches "pulsatile radial forces on the structure," which holds the same meaning to a person of ordinary skill in the art.

Additionally, Applicants argue that "St. Ville teaches away from the system of claim 1." This argument is unpersuasive because the support for Applicants' argument suggests that St. Ville teaches a *different feature* than the claimed feature. This evidence does not support a conclusion that the prior art *teaches away* from the claimed feature. This argument is unpersuasive.

Additionally, Applicants argue that it would not have been obvious to combine St. Ville with Whitcher. This argument has been considered but is moot because the previous rejection is withdrawn.

Regarding claims 2, 17, and 32; and 5 and 7; and 20 and 22; and 33 and 35; and 58 and 60; and 74 and 76; and 88 and 90; Applicants submit similar arguments which have been addressed above.

Regarding claims 6, 21, 34, 59, 75, and 89, Applicants argue that "neither Whitcher nor St. Ville teach or suggest an endovascular prosthesis in the form of a stent graft." This argument is unpersuasive because Whitcher clearly teaches a stent graft [*"Simulation of* in vivo *loading conditions of nitinol vascular stent structures"* (Whitcher, title); and throughout the reference].

Regarding claims 9, 24, 36, 62, 78, and 91; and 10, 25, 37, 63, 79, and 92; and 67, 83, 96, 112, 114, and 116; Applicants submit similar arguments which have been addressed above.

Regarding claims 14, 29, 41, 68, 84, and 97; and 15, 30, 42, 69, 85, and 98, Applicants submit similar arguments which have been addressed above.

Additionally, Applicants remark that "Whitcher does not appear to disclose a visualization tool that includes interactive software for visualizing finite element analysis results of three-dimensional grids as recited in rejected claims 15, 30, 42, 69, 85, and 98. Applicants respectfully request clarification as to whether the Examiner is taking official notice of such teaching, asserting inherency of such teaching or the like so that Applicants may respond with more specificity."

The Examiner submits that Whitcher clearly teaches "a visualization tool that includes interactive software for visualizing finite element analysis results of three-dimensional grids" as

recited in the claims at issue [*"**FE model output was often manipulated and displayed** utilizing the Perl data extraction and manipulation language and the 'gnuplot' data graphics system (Free Software Foundation, Cambridge, MA)."* (page 1008, "2. CAD Interface"); (Figure 3)]. For Applicants' clarification, the Examiner is not relying upon neither Official Notice nor inherency, but rather the explicit teachings of the reference.

Regarding claims 113, 115, 117, 118, and 119, Applicants submit similar arguments which have been addressed above.

Regarding claim 124, Applicants submit similar arguments which have been addressed above.

Additionally, Applicants argue that "the previous Office Action maintains that a 'Goodman fatigue analysis' is well known to those of ordinary skill in the art for predicting long term structural integrity by recreating a plurality of dynamic and contraction cycles ("alternating stress"). If official notice is being made as to this assertion, this should be so stated with the provision of documentary evidence. [...] Applicants assert that without supporting documentary evidence, the assertion regarding Goodman fatigue analysis is improper and Applicants respectfully request clarification."

As can be seen from the statement of the rejection, the Examiner has not relied upon Official Notice. Instead, the Examiner has relied upon the explicit teachings of the reference, specifically [*"In the Symphony nitinol design, the principal use of the finite-element (FE) calculations is prediction of material fatigue life."* (page 1005, "1. Introduction"); *"The model in*

consideration indicates peak tensile stresses in the region directly opposite the contact area (see Fig. 6). These values are used for generating data good for a Goodman diagram fatigue analysis. The results accurately predict experimental fatigue test results, both for specimens tested to failure and those tested within the designed operating range." (page 1011, "8. Results")]. The Examiner's comments regarding the Goodman diagram illustrated the Examiner's interpretation of the reference.

Applicants have in no way alleged or suggested that the prior art fails to teach the claimed limitation, but instead have requested clarification as to whether or not the Examiner relied upon Official Notice. The Examiner did not rely upon Official Notice in the previous rejection of claim 124.

Regarding claim 125, Applicants submit similar arguments which have been addressed above.

Regarding claims 4, 19, 57, and 73, Applicants argue primarily that DiGioia does not teach "acquiring three-dimensional volumetric data of an anatomical feature of a vascular system". DiGioia was not relied upon for providing this teaching. The rejection is withdrawn for reasons set forth above.

Regarding claims 8, 23, 61, and 77, Applicants argue that "Lee does not appear to teach a software application which generates surface points from three dimensional volumetric data which are then converted into stereolithography, slice files, IGES files or a combination thereof".

This argument is unpersuasive because, as cited in the previous Office Action, Lee explicitly teaches [*"Images were acquired using a two-dimensional (2D) vascular time-of-flight technique."* (Lee, page 1, left column); *"Once cross-sectional contours were obtained for each image, CTM (a module of Mimics) used a cubic spline to determine the contours at axial locations between each image. A* **slice file** *with the scaled-up 3D geometric information was generated as a set of contours."* (Lee, page 1, right column); etc.].

Regarding claims 11-12, 26-27, 38-39, 64-65, 80-81, and 93-94, Applicants argue that Raboin does not teach simulating an interaction between an anatomical feature and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. This argument is unpersuasive because Raboin was not relied upon for such teachings, and because other prior art references teach those features as shown above.

Regarding claims 55, 71, 87, and 120-123, Applicants submit similar arguments which have been addressed above.

Additionally, Applicants argue that "it is not clear that Sorensen discloses simulating stresses/strains/deformations to a point of failure. Although Weibull failure probability calculations, incorporating FEA stress profiles are discussed, simulation to a point of failure is not. In addition, the identification of the location of maximum principle tensile stresses and the correlation of such locations with fractographic observations does not require simulation to a point of failure."

This argument is unpersuasive because of the explicit teachings of Sorensen such as [*"Failure origins of the FPDs are listed in the Table. Failures were seen to originate from either the external surface of the connector (free surface origin) or from the core-veneer interface within the gingival portion of the connector (interface origin)."* (Sorensen, page 1255, "Results"); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed (i.e., no tooth rotation allowed)... Allowing the abutment tooth to rotate about a dentin node within the root portion of the model produced the stress results shown in Fig. 4. The stress distributions in Figs. 3 and 4 are distinctly different. With rotation allowed (Fig. 4), the FEA solution is in close qualitative agreement with the fractographic findings, i.e. that all failures originated from the connectors and quite often from the core-veneer interface."* (Sorensen, pages 1255-1256, "Results")].

Additionally, Applicants argue that "claim 122 is directed to the method of claim 120 further including varying one or more in vitro failure mode test parameters based on an additional step of comparing simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data representing said anatomical feature and additional simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said in vitro failure mode test. Claim 123 includes the limitations of claim 122 and recites that the one or more in vitro failure mode test parameters include test frequency."

Regarding claim 122, Sorensen teaches the claimed feature [*"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed (i.e., no tooth rotation allowed)... Allowing the abutment tooth to rotate about a dentin node within the root portion of the model*

produced the stress results shown in Fig. 4. The stress distributions in Figs. 3 and 4 are distinctly different. With rotation allowed (Fig. 4), the FEA solution is in close qualitative agreement with the fractographic findings, i.e. that all failures originated from the connectors and quite often from the core-veneer interface." (Sorensen, pages 1255-1256, "Results")].

Regarding claim 123, Sorensen teaches the claimed feature [*"N = total sample number"* (Sorensen, page 1256, "Results")].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

4. Claims 1-3, 5-7, 9-10, 14, 15, 112-113; 16-18, 20-22, 24-25, 29, 30, 114-115; 31-37, 41, 42, 116-117; 54, 56, 58-60, 62-63, 67-69, 118; 70, 72, 74-76, 78-79, 83-85, 124-125; 86, 88-92, 96-98, 119, 124, and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Simulation of *in vivo* loading conditions of nitinol vascular stent structures" by F. D. Whitcher in view of "A Prototype Simulator for Endovascular Repair of Abdominal Aortic Aneurysms" by C. K. Chong et al. ("Chong").

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, Whitcher teaches a computer system including at least one processor and memory for analyzing medical devices [*"Vascular support structures are an important tool for treating arteriosclerosis.... This paper describes the simulation analysis of vascular support structures (stents), to provide designers with estimates of their* in vivo *structural behavior and fatigue properties."* (abstract); *"The stent-simulation work used relatively simple and inexpensive CAD systems with a high degree of analyst productivity."* (abstract)], comprising:

A stress/strain/deformation analyzer [*"The finite-element material model used in the stent simulation was a Von Mises yield-criterion elastic-plastic model using the ADINA 27Onode element and mixed displacement-pressure formulation [2]."* (Whitcher, page 1008, "3. Material

Model/Element Formulation")] that receives a finite element model or mesh, material properties of an anatomical feature(s) and a medical device, load data on said anatomical feature(s), and/or said medical device [See Fig. 3, Fig. 5 and related description; pages 1008-1009, sections 3-5, etc.] and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s) [*"In the arteries, the cyclical difference between systolic and diastolic pressures generates the most significant forces on the stent… The loading conditions for this analysis therefore consider only the preload and pulsatile radial forces on the structure (see Fig. 5)…The stent-size indication matrix was analyzed for worst-case fatigue conditions. The maximum arterial cyclic expansion due to systolic/diastolic pressure differentials is 5% [6]. The mean stress loading will be highest in a calcified lesion, in which case the cyclic loading will be small as the Young's modulus of calcific plaque is two orders of magnitude higher than that of either healthy tissue or fibro-fatty plaque. In a compliant vessel, the vessel will expand in response to the stent expansion force, reducing the mean stress. The composite structure will be less compliant in systolic/diastolic loading, resulting in lower cyclic strains."* (page 1009, "5. Boundary and Loading Conditions", "6. Fatigue Analysis")].

Whitcher teaches a generated geometric model of said anatomical feature(s) and a mesh model of a medical device [See Fig. 3, Fig. 5; page 1009, "5. Boundary and Loading Conditions"; etc.].

Chong teaches a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature(s) and generates a geometric model of said anatomical feature

["*Triangulated surfaces of a simplified AAA computer model having renal, common iliac, external iliac, internal iliac and femoral arteries. All the arterial segments lie on the same plane.*" (Caption, Fig. 1, page 331); "*Three-dimensional computer model of a patient's AAA treated with a bifurcated endovascular stent-graft. This model was reconstructed from the patient's preoperative spiral CT scan images.*" (Chong, Caption, Fig. 2, page 331)]; and

A mesh generator that receives said geometric model of said anatomical features and generates a finite element model or mesh representing said anatomical features (Chong, Captions, Figs. 1 and 2, page 331).

Whitcher and Chong are analogous art because both are directed to endovascular stents and computer modeling.

It would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Whitcher and Chong to arrive at the claimed invention because Chong expressly teaches that properly performing a stent-graft procedure can save a human's life [*"Abdominal aortic aneurysm (AAA) affects 3-6% of the elderly population over 65 years. In England and Wales approximately 10,000 people die each year from rupture of their AAAs. Surgical repair of the aneurysm, preferably before rupture, offers the best chance of averting death from this cause."* (Chong, "Introduction", page 330); *"Highly developed skills in guidewire and catheter techniques are required along with particular knowledge and understanding of the specific device and introducer system being used."* (Chong, "Introduction, page 330)]. Whitcher complements this motivation by teaching that *in vivo* studies of the support structure lead to improved patient outcomes [*"Long-term studies of the clinical outcome of coronary bypass surgery and balloon angioplasty conclude that the five year outcome and*

monetary cost of these two treatment methods are virtually identical. Early studies of vascular support structures known as stents provided the promise of substantially improved patient outcomes. As such, there is a high priority to deliver high-performance vascular stents to the health-care practitioner." (Whitcher, "Introduction", page 1005)]. Therefore, in order to provide the highest quality endovascular stent with the greatest likelihood of saving a patient's life, a person of ordinary skill in the art would be motivated to combine the teachings of Whitcher and Chong.

In forming that combination, a person of ordinary skill in the art would recognize that Whitcher is directed to *in vivo* loading conditions of nitinol vascular stent structures (Whitcher, title). "In vivo" loading conditions of the stent structure refers to the loading conditions experienced by the stent when it is surgically placed in a patient's vascular system. In that regard, Whitcher is specifically concerned with the "pulsatile radial forces on the structure" (Whitcher, "5. Boundary and Loading Conditions", page 1009). These are the "pulsation" forces experienced due to the patient's heartbeat, i.e., the expansion and contraction of the vessel due to the diastolic and systolic blood pressure. Therefore, Whitcher clearly teaches that the interaction between the medical devices ("stent") and the anatomical feature (the vessel in which the stent is placed) must be studied in order to provide the highest quality stent, which in turn increases the likelihood of saving a patient's life.

While Whitcher's method teaches an *approximation* of the blood vessel (See Whitcher, "5. Boundary and Loading Conditions"), Chong teaches an *explicit finite element model of the abdominal aortic aneurysm* (See Chong, Figs. 1 and 2). Chong clearly teaches a model of the anatomical feature with higher accuracy and higher fidelity than is considered by Whitcher.

Therefore, being motivated to combine the teachings of Whitcher and Chong (as established above), it would have been obvious to a person of ordinary skill in the art to combine Chong's *explicit finite element model of the abdominal aortic aneurysm* with Whitcher's *finite element model of the stent structure* to arrive at a combined *finite element model* of an *in vivo stent placed within the abdominal aortic aneurysm*. This combination would result in a model with higher accuracy and higher fidelity, and with a greater capability to predict the *in vivo loading conditions of the nitinol vascular stent structure*. As a result, a higher quality stent could be designed, which would increase the likelihood that a patient's life could be saved or prolonged.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Whitcher and Chong to arrive at the invention specified in claim 1.

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 Chong teaches that the geometric model of said anatomical features is an idealized geometric model [*"Triangulated surfaces of a simplified AAA computer model having renal, common iliac, external iliac, internal iliac and femoral arteries. All the arterial segments lie on the same plane."* (Caption, Fig. 1, page 331); *"Three-dimensional*

computer model of a patient's AAA treated with a bifurcated endovascular stent-graft. This model was reconstructed from the patient's preoperative spiral CT scan images." (Chong, Caption, Fig. 2, page 331)];.

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 2.

Regarding claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90, Whitcher teaches that the prosthesis is an endovascular prosthesis, a stent graft, and a cardiovascular stent (abstract).

Regarding claims 9, 24, 36, 62, 78, and 91, Chong teaches that the mesh generator includes three-dimensional finite modeling software [*"Triangulated surfaces of a simplified AAA computer model having renal, common iliac, external iliac, internal iliac and femoral arteries. All the arterial segments lie on the same plane."* (Caption, Fig. 1, page 331); *"Three-dimensional computer model of a patient's AAA treated with a bifurcated endovascular stent-graft. This model was reconstructed from the patient's preoperative spiral CT scan images."* (Chong, Caption, Fig. 2, page 331)].

Regarding claims 10, 25, 37, 63, 79, and 92, Whitcher teaches that the stress/strain/deformation analyzer is a non-linear finite element modeling software [*"The analyses presented here were run principally using the ADINA direct solver."* (page 1009, "7. Solution")].

Regarding claims 67, 83, 96, 112, 114, and 116, Whitcher teaches that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses strains, and deformations of said medical device [*"The analyses presented here were run principally using the ADINA direct solver."* (page 1009, "7. Solution")].

Regarding claims 14, 29, 41, 68, 84, and 97, Whitcher teaches a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation [*"FE model output was often manipulated and displayed utilizing the Perl data extraction and manipulation language and the 'gnuplot' data graphics system (Free Software Foundation, Cambridge, MA)."* (page 1008, "2. CAD Interface"); (Figure 3)].

Regarding claims 15, 30, 42, 69, 85, and 98 Whitcher teaches that said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids [*"FE model output was often manipulated and displayed utilizing the Perl data extraction and manipulation language and the 'gnuplot' data graphics system (Free Software Foundation, Cambridge, MA). These tools allowed rapid evaluation of the large FE data sets."* (page 1008, "2. CAD Interface)].

Regarding claims 113, 115, 117, 118, and 119, Whitcher teaches that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-

static stresses, strains, and deformations [*"The loading conditions for this analysis therefore consider only the preload and pulsatile radial forces on the structure (see Fig. 5)."* (Whitcher, "5. Boundary and Loading Conditions", page 1009)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

Regarding claim 124, Whitcher teaches long term structural integrity testing of said medical device by recreating a plurality of dynamic expansion and contraction cycles of the vascular system [*"In the Symphony nitinol design, the principal use of the finite-element (FE) calculations is prediction of material fatigue life."* (page 1005, "1. Introduction"); *"The model in consideration indicates peak tensile stresses in the region directly opposite the contact area (see Fig. 6). These values are used for generating data good for a Goodman diagram fatigue analysis. The results accurately predict experimental fatigue test results, both for specimens tested to failure and those tested within the designed operating range."* (page 1011, "8. Results")]. A "Goodman diagram fatigue analysis" is well known to those of ordinary skill in the art for predicting long term structural integrity by recreating a plurality of dynamic expansion and contraction cycles ("alternating stress").

Regarding claim 125, Whitcher teaches that the plurality of dynamic expansion and contraction cycles of the vascular system comprise an amount of cycles that would meet or exceed the amount of cycles that would be expected in the individual's lifetime.

5. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of Chong as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

Whitcher in view ofChong does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure."* (column 7, lines 8-14)].

Whitcher in view of Chong and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of Whitcher in view of Chong because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

6. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of Chong as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

Whitcher in view of Chong does not expressly disclose that the geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

Whithcer in view of Chong and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of Whitcher in view of Chong because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

7. Claims 11-12, 26-27, 38-39, 64-65, 80-81, and 93-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of Chong as applied to claims 9-10, 24-25, 36-37, 62-63, 78-79, and 91-92 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claim 11, Whitcher in view of Chong does not expressly disclose that the three-dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

Whitcher in view of Chong and Raboin are analogous art because both are directed to modeling of prosthetics.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of Whitcher in view of Chong because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 26, 38, 64, 80, and 93 reiterate the limitations of claim 11 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 11.

Claims 12, 27, 39, 65, 81, and 94 have been previously interpreted as recited features inherent in DYNA3D and NIKE3D and are therefore rejected for rationale similar to that given above for claim 11. (See Office Action, 7 February 2006, page 5)

8. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of Chong as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, Whitcher in view of Chong does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles… Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed…"* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

Whitcher in view of Chong and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Whitcher in view of Chong because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, Whitcher in view of Chong does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate… This result corresponds more closely to the fractographic findings* [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations…"* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for*

data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the in vitro *data were simply evaluated…"* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

Whitcher in view of Chong and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Whitcher in view of Chong because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason Proctor/
Examiner
Art Unit 2123

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